This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: December 21, 2001

510(k) number: K020047

APR - 5 2002

Applicant Information:
Rubicor Medical, Inc.
849 Veterans Blvd.
Redwood City, CA 94063.

Contact Person: Ary Chernomorsky
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification:	Class II
Trade Name:	Rubicor Breast Biopsy Device
Classification Name:	Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Neothermia En Bloc Biopsy System (K003190), the Ethicon Mammotome Hand-Held System (K991980) and the USSC Autosuture Endo Catch (K922123).

Intended Use:
The Rubicor Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedure.

The Rubicor Breast Biopsy Device is to be used for diagnostic purposes only and is not intended for therapeutic uses.

Test Results:
Performance
Results of in-vitro testing demonstrate that the Breast Biopsy Device is safe and effective for its intended use.

Biocompatibility
The materials used in the Rubicor Breast Biopsy Device meets the requirements of ISO 10993-1.

Summary: Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ary Chernomorsky
Vice President, Research and Development
Rubicor Medical, Inc.
849 Veterans Boulevard
Redwood City, CA 94063

APR - 5 2002

Re: K020047
Trade/Device Name: Rubicor Breast Biopsy Device
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 4, 2002
Received: January 7, 2002

Dear Mr. Chernomorsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K020047

Device Name: Rubicor Breast Biopsy Device

Indications for Use:

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The Rubicor Breast Biopsy Device is to be used for diagnostic purposes only and is not intended for therapeutic uses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020047

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)